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DISTRACTION AND DAMPING SYSTEM WHICH CAN BE ADJUSTED AS THE VERTEBRAL COLUMN GROWS

Field of the Invention

The invention relates to an adjustable distraction and support device implanted on the trunk of a child incorporating a combination of several devices used to straighten, support and cushion the mechanical stresses and which can be readjusted according to the growth of the child, these functions not being attainable through the use of each device separately.

Background of the Invention

Patent Fr 9907034, directed toward a chest wall distractor, describes and claims a mechanical device that can monitor the growth of the bones in incorrect formation while correcting the deformities of the trunk without prohibiting or obstructing the patient's growth, but it is limited in its application to a deformity at the level of the thorax; it cannot be applied to a deformity involving the lumbar spine of the child since his or her growth could be impaired by placing the device directly on the vertebrae.

Patent Fr 109628000, entitled *Flexible vertebral linking device consisting of elements that allow the overcoming of a spinal deformity*, is largely a cushioning device comprised of rigid components holding visco-elastic means that can cushion the mechanical stresses in the preferred directions.

This device was designed to offset the stresses sustained by the vertebrae of the human body in a multi-axial fashion; it was not intended to be lengthened during displacements by stretching as is the case of the device described in the previous patent.

Summary of the Invention

The device of the present invention allows the steadying of the thorax while allowing the lungs to develop, the straightening of the spine completely during growth without blocking the vertebrae, the cushioning of the external mechanical stresses, the use of an adjustment system that can be accessed easily and does not require a extensive or invasive surgical procedure.

The anchoring devices of the first device resulting from the first invention (patent Fr 9907034) are formed through the use of anchoring brackets surrounding the bones; this first device lending itself perfectly to the fasteners of the thorax would however exert considerable stress on the fasteners used to secure the lumbar vertebrae, which would lead to a risk of rupture in particular for the anchoring screw, which is, of course, unacceptable.

The present invention solves this problem because of its capacity to resolve the difficulties stemming from large deformities by including the lumbar spine.

In the search report for the French patent application (filing 0210248), three prior documents are compared. In U.S. Patent No. 6,402,750 B1, the only comparable device is the piston, which in this invention can only move axially, it being unable to follow a curvilinear path in phase with the shape of the spine. For an adjustment, this device has to be completely dismantled, which requires a major surgical procedure. In no way is this the case for our invention, which requires only a minor surgical procedure under local anesthesia in order to adjust a central means, the access to which requires only a small incision made under the skin.

Patents FR 2794357 and FR 2814936, dealing firstly with two devices designed independently and that could not be combined without being modified, demonstrates to a person skilled in the art the non-obviousness of this combination, and therefore constitutes a proof of inventiveness. The result that was obtained was not guaranteed in any way. It was made possible as a result of the creation and implantation of new means such as toothed rods, which can be bent as needed and one of the ends of which is shaped like a piston. The unexpected result was the smooth operation of the device, showing that the implementation of this invention combining two prior devices was carried out following numerous tests performed with various radii of rod curvature, characteristics that are distinguished from the prior art.

Brief Description of the Drawings

The following drawings may aid a better understanding of the invention:

Fig. 1 is a distraction device intended for the bones of children (prior art).

Figs 2A and 2B are a flexible and cushioning connecting device consisting of two rods, one of which includes teeth to be used as a pinion (rectilinear or curved rods).

Fig. 3 is the first example of a device which combines the distraction device intended for the child's bones with the flexible and cushioning connecting device.

Fig. 4 is the second example of the device which combines the distraction device with two flexible and cushioning connecting devices.

Fig. 5 is a device which combines both devices placed on a rib and on a vertebra and includes two curvilinear distraction rods.

Fig. 6 is another example of the device implemented on a rib and a vertebra and including rectilinear and curvilinear distraction rods.

Fig. 7 is a device working with rectilinear rods.

Fig. 8 is the placement of the device on a deformed trunk.

Fig. 9 is a view of the device following the straightening of the initially deformed trunk with the cushioning device positioning itself crosswise under the influence of the straightening forces.

Fig. 10 is a view of the compound device, the cushioning device being less strained due to the child's growth.

Fig. 11 shows the placement of several devices on a trunk in order to completely control and straighten the trunk.

Detailed Description of the Invention

Device 2, combining devices 3 and 1, consists of a device 3 called the distraction device intended for children's bones and of a device 1 called device for cushioning the mechanical stresses.

The device 2 (Fig. 3) thus formed allows simultaneously the straightening of the spine and steadying of the trunk of a child, the monitoring growth and the lengthening of the anchoring distances by minor surgical procedures, the alleviation of the mechanical loads exerted via anchoring means, the cushioning of the mechanical stresses.

This invention can be better understood if we recall briefly the means used in devices 3 and 1.

Device 3 allows the monitoring of the course of the deformity of a child's trunk; it can be implanted in the human body easily, due to its small size.

Two toothed rods 35 and 36 mounted on a central means 300 equipped with a hole 312 through which a tool can be inserted to adjust the distance from the anchoring devices 231 to the bones; the device is locked in place in a position determined by tightening the two screws 341 and 342 located on the central means 300.

As shown in the prior art, rods 35 and 36 were rectilinear and could have curved ends to ease placement of the anchoring devices, while the present device 2 may include arched or curved rods 35c and 36c, along their entire length. In this case, test results have shown a normal operation of the device. The advantage gained from this improvement is that damage to the surrounding tissues can be avoided by lengthen the anchoring distances by carefully following a curvature chosen at the beginning by the operator. Moreover, this curvature may be adjusted due to the malleability of the material constituting the rods, which, after testing, can be deformed by the operator.

The flexible intervertebral linking device 1 is itself comprised of two sets of means a first set of means 11 comprised of rigid means 110, 130, and 37 made of biocompatible material assuring a good mechanical bond of the device by transmitting the stresses completely without being deformed, and second set of means 12 made of flexible and cushioning means 121 and 122 made of biocompatible visco-elastic material, accepting repeated elastic deformations, the combination of both sets of means allowing the withstanding and cushioning of the mechanical stresses to which it will be subjected, in order to overcome any dysfunction in the spinal linkage.

Each of devices 3 and 1 have means which are compatible by their design and main functions to which are added new means allowing them to be combined.

As we have already mentioned, device 3 can receive rectilinear or curvilinear rods that are curved at various radii. A device 2 can be positioned consisting of a device 3 having a rectilinear rod 37 on one side, and a curved or arched rod 36c on the other side.

In this latter case, 36c is curved to avoid causing injury and to allow lengthening near the anatomic curve (Fig. 6). Device 2 resulting from the combination of devices 3 and 1 allows the straightening of the trunk by adjustment of the central means 300 and its means 312, 341 and 342 through a highly targeted, surgical procedure only slightly invasive and performed under local anesthesia.

The distraction device 2 includes at least one rectilinear or curvilinear toothed rod 37 or 37c, one end of which includes a cylindrical plate 370 perfectly integrated into the visco-elastic means 121 and 122 and rigid means 130 of device 1, allowing the distraction device 2 to be cushioned and to cling to a vertebra even though beforehand it is out of alignment with the distraction device 3.

Thus, the trunk is straightened with the central means 300, which is locked into place with screws 341 and 342 using a small Allen wrench inserted in screw 312 through a

small opening requiring only minor surgery. Device 2 can then perform its function of supporting the straightened trunk.

After growth, device 2 is examined and in particular the alignment of rod 37 with rod 110; the operator may then modify means 300 in an effort to straighten the trunk again. Following the straightening efforts, the cushioning device 1 that is part of device 2 is positioned slightly crosswise (Fig. 9), thus serving as a growth and force indicator to determine the straightening needs on a case by case basis. In the case where a device 2 is positioned on the trunk of a child at the beginning of growth, the cushioning device 1 can be placed between a screw anchoring to a vertebra and rod 37 designed to ensure the linkage with device 3 (Fig. 9, Means 232). This device 2 authorizes and allows the monitoring of the child's growth while preventing significant stresses being exerted on the anchoring screw 232 (Fig. 10). By absorbing the shocks and the dynamic stresses in said bone screws 232, the visco-elastic means 121 and 122 will avoid ruptures. The shift to the "alignment" position of rods 110 with 37 or 37c is a reliable indicator.

If both rods are aligned, it is again necessary to restore the tension to the device since the stresses applied to device 1 have decreased and the two rods are again on the same axis as a result of the elasticity of device 1 and of the growth of the child.

In addition to the limitations on the stresses exerted on the screws following the straightening of the trunk, device 1 cushions the exterior mechanical stresses and as a result its flexibility will not restrict vertebral mobility.

The various straightening and steadying maneuvers on a child's trunk can easily be repeated; consequently, device 2 may be adjusted as many times as is necessary through a highly localized procedure performed on means 300.

In addition, the multiple combinations of means 1 and 3 allow placing several devices 2 on the spine (Fig. 11) to monitor the growth and straighten the trunk.